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Citation for the original published paper (version of record):
Rigato, C., Reinfeldt, S., Håkansson, B. et al (2019). Effect of transducer attachment on vibration transmission and transcranial attenuation for
direct drive bone conduction stimulation. Hearing research, 381: 107763-.
http://dx.doi.org/10.1016/j.heares.2019.06.006

Hearing Research 381 (2019) 107763

Contents lists available at ScienceDirect

Hearing Research

journal homepage: www.elsevier.com/locate/heares

Research Paper

Effect of transducer attachment on vibration transmission and transcranial attenuation for direct drive bone conduction stimulation

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A R T I C L E I N F O

Article history:
Received 1 March 2019
Received in revised form
20 June 2019
Accepted 27 June 2019
Available online 12 July 2019

A B S T R A C T

Direct drive bone conduction devices (BCDs) are used to rehabilitate patients with conductive or mixed hearing loss by stimulating the skull bone directly, either with an implanted transducer (active transcutaneous BCDs), or through a skin penetrating abutment rigidly coupled to an external vibrating transducer (percutaneous BCDs). Active transcutaneous BCDs have been under development to overcome limitations of the percutaneous bone anchored hearing aid (BAHA), mainly related to the skin penetration. The attachment of a direct drive BCD to the skull bone can differ significantly between devices, and possibly influence the vibrations' transmission to the cochleae.

In this study, four different attachments are considered: (A) small-sized flat surface, (B) extended flat surface, (C) bar with a screw at both ends, and (D) standard bone anchored hearing aid screw. A, B, and C represent three active transcutaneous options, while D is for percutaneous applications. The primary aim of this study was to investigate how the different transcutaneous attachments (A, B, and C) affect the transmission of vibrations to the cochleae to the ipsilateral and the contralateral side. A secondary aim was to evaluate and compare transcranial attenuation (TA, ipsilateral minus contralateral signal level) between transcutaneous (A, B, and C) and percutaneous attachments (D).

Measurements were performed on four human heads, measuring cochlear promontory velocity with a LDV (laser Doppler vibrometer) and sound pressure in the ear canal (ECSP) with an inserted microphone. The stimulation signal was a swept sine between 0.1 and 10 kHz. The comparison of ipsilateral transmission between transcutaneous adaptors A, B, and C was in agreement with previous findings, confirming that: (1) Adaptor C seems to give the most effective transmission for frequencies around 6 kHz but somewhat lower in the mid frequency range, and (2) keeping a smaller contact area seems to provide advantages compared to a more extended one. The same trends were seen ipsilaterally and contralaterally. The observed TA was similar for adaptors A, B, and C at the mastoid position, ranging -10-0 dB below 500 Hz, and 10–20 dB above. A lower TA was seen above 500 Hz when using adaptor D at the parietal position.

1. Introduction

Bone conduction (BC) is one way of stimulating the cochlea and elicit a hearing sensation which can be considered alternative or complementary to air conduction (AC). In subjects with normal hearing, these two ways coexist, and the inner ear stimulation is the result of sound waves transmitted through the outer and the middle ear as well as through bones, tissues, and fluids of the skull.

Sound propagation by BC is widely used to rehabilitate patients

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https://doi.org/10.1016/j.heares.2019.06.006

when the hearing impairment originates in the outer or middle ear. This is achieved with bone conduction devices (BCDs), transmitting vibrations directly to the cochlea via the skull bone and surrounding tissues, thus bypassing the potentially impaired areas of the hearing organ. BCDs are preferably used to rehabilitate patients with conductive or mixed hearing loss, but also single-sided deafness (SSD) can be effectively treated (Reinfeldt et al., 2015a).

Among the great variety of BCDs clinically available, two main groups can be distinguished based on whether the stimulating unit, often referred to as actuator or transducer, is in contact with the skin, named skin-drive BCDs, or directly with the skull bone, named direct drive BCDs (Reinfeldt et al., 2015a). The main advantage with direct-drive stimulation is that there is no need for applying a constant static pressure against the skin to achieve a good transmission of the vibrations, thus avoiding potential complications such as numbness and discomfort (den Besten et al., 2018; Estrem and Thelin, 1988; Reinfeldt et al., 2015a). Furthermore, with a direct-drive stimulation, the transmitted signal is not dampened by the passage through the skin and soft tissues and the transmission efficiency is consequently higher (Håkansson et al., 1985; Mattingly et al., 2015; Stenfelt, 2006). However, such BCDs require the patient to undergo surgery to have the device implanted.

The first developed direct-drive BCD was the bone anchored hearing aid (BAHA), consisting of a single casing, including audio processing and stimulating unit, coupled to a skin penetrating abutment rigidly anchored to the skull bone with a screw. BAHAs are referred to as percutaneous devices, as they require a permanent skin penetration. This is in turn their greatest limitation, for medical and cosmetic reasons, although more recent implant design and surgical procedures have significantly reduced the incidence of abutment-related complications (den Besten et al., 2016; Kruyt et al., 2017; Kruyt et al., 2019; Nelissen et al., 2016; Verheij et al., 2016). Over the last years, alternatives to the BAHA are being developed, combining the advantages of direct-drive stimulation with those of keeping the skin intact. This is possible with the so-called active transcutaneous devices, consisting of two parts: an externally worn audio processor, and an implanted unit located under intact skin. The implanted unit comprises a transducer that is attached directly to the skull bone and is electrically driven wirelessly via an induction link. Examples of active transcutaneous BCDs are the clinically available Bonebridge™ from MEDEL (Innsbruck, Austria) and the experimental BCI (bone conduction implant), currently in an advanced stage of its clinical trial (Håkansson et al., 2010; Reinfeldt et al., 2015b).

Among other aspects, the coupling mechanism between a direct drive BCD and the skull bone can differ significantly between devices. In the percutaneous BAHA, the stimulation is conveyed via a 4.5 mm in diameter osseointegrated screw which can be regarded as a single point stimulation. In active transcutaneous solutions, instead, the contact to bone is achieved via flat contact surface in the case of the BCI, and double point contact in the Bonebridge™ design. An optimal coupling of the device to the bone can ensure a more efficient transmission of the stimulus to the bone and ultimately to the cochlea and is therefore considered to be of clinical interest to study the coupling influence on the vibration transmission.

In a previous study, the effect of varying the contact to bone was investigated for active transcutaneous BC stimulation (Rigato et al., 2018) with three different attachment typologies: (A) a flat circular contact surface with small size, (B) a flat circular contact surface with larger diameter, and (C) a double point contact via screws on either side of a rigid bar. That study was limited to ipsilateral transmission, i.e. to the cochlea closest to the stimulation site. The results seemed to indicate a better performance of the double screw attachment over the flat surfaces for frequencies between 5 and 7 kHz, and that keeping a smaller contact surface may be beneficial for vibration transmission at mid and high frequencies. In the present study, the percutaneous BAHA attachment typology and position are also measured to provide a reference and an additional comparison and reference to the traditional BAHA position. The BAHA screw attachment may be relevant for a potential future active transcutaneous application as well. In fact, in a recent article by Dobrev et al. (2018), the possibility of anchoring an implanted transducer via an osseointegrated screw in that position is introduced.

In the current study, the comparison between the attachment types includes both ipsilateral and contralateral transmission. As opposed to conventional air conduction devices, where only the fitted side is affected, BCDs stimulate both cochleae at the same time but with a frequency dependent difference in amplitude and phase. Therefore, measurements on both ipsilateral and contralateral side are relevant when evaluating the rehabilitation effect of a BCD. If the BCD is implanted on the side affected by the conductive or mixed hearing loss, the better the transmission to the ipsilateral side, the greater the ability of the device to provide a sufficient rehabilitation effect. When looking at the contralateral transmission, however, the interpretation can be twofold. A high transmission to the contralateral side can be seen as a desirable characteristic, to increase the overall amplification or when the device is used in SSD patients, where the deaf side is otherwise in a sound shadow. However, having a more side-specific stimulation could lead to benefits in spatial hearing ability, where interaural level difference (ILD) is an important cue (Grothe et al., 2010; Middlebrooks and Green, 1991). One way of quantifying the side-specificity of the stimulation is to measure the transcranial attenuation (TA) in dB, obtained as the difference in signal level between the ipsilateral side and the contralateral one given the same stimulation position and intensity. A positive TA indicates lower levels at the contralateral side, thus a more side-specific stimulation, while a neutral or negative TA indicates comparable transmission on both sides. TA has been investigated in previous studies on patients (Nolan and Lyon, 1981; Snyder, 1973; Stenfelt, 2012) and on cadavers (Dobrev et al., 2018; Eeg-Olofsson et al., 2008; Håkansson et al., 2010; Stenfelt and Goode, 2005). The general trend seen in these studies is that TA depends greatly on frequency and stimulation position and tends to increase with increased frequency and for stimulation position closer to the ipsilateral cochlea. How TA is affected by the way the transducer is anchored on the skull bone has not been studied yet, which is why it is investigated in this study.

2. Aim of the study

The primary aim of this study was to investigate the effect of transducer attachment on vibration transmission to cochleae on the ipsilateral and contralateral side, intended for application in transcutaneous direct drive devices. A secondary aim was to evaluate and compare TA between three different attachments implanted in the mastoid bone, and between these three attachments and the BAHA screw.

Specifically, the following research questions were addressed:

(1) How does a flat transducer to bone contact compared to a twin-screw attachment affect the transmission of vibrations
  a. To the ipsilateral cochlea?
  b. To the contralateral cochlea?
(2) How does the size of the flat contact surface affect the transmission to ipsilateral and contralateral cochleae?
(3) How does the TA change with the aforementioned differences in attachment method?

(4) How does the TA in the aforementioned cases compare to the values obtained from a stimulation via BAHA screw at the conventional BAHA position in the parietal bone?

3. Materials and methods

The study was approved by the Regional Ethics Committee.

3.1. Subjects

Measurements were performed on four human cadaveric heads (3 males, 1 female). Three of them were freshly frozen and defrost prior to the measurements, one was embalmed (perfusion with 62% ethanol and 35% glycerol, with added potassium sorbate 0.3 g/l) and kept in a refrigerated cell. The size ranged between 53 and 58 cm in circumference. No signs of previous surgery nor damages to the skull structure or hearing organ were detected at visual inspection. The samples were held in a resting position by a donut shaped pillow during the measurements, providing stability and vibrational decoupling from the stainless-steel table underneath.

The total data acquisition over the four specimens was completed in a span of 30 h, with an interruption of approximately 10 h when the samples were stored in a refrigerated cell.

3.2. Stimulation

The vibrations were produced by a balanced electromagnetic separation transducer (Håkansson, 2003) electrically driven by a signal generator (Agilent 35670A, Agilent Technologies, Inc., CA, USA) with a swept sine wave from 0.1 to 10 kHz and at a constant input voltage of 500 mVrms. The transducer was calibrated on a skull simulator (TU-1000, Nobelpharma, Göteborg, Sweden) (Håkansson and Carlsson, 1989) and its output force level characteristics were used to normalize the measured data.

The transducer was rigidly coupled via an M2-threaded screw to the backside of four different adaptors to obtain four typologies of transducer-to-bone contact: (A) small-sized flat surface of 6 mm in diameter, (B) extended flat surface of 19 mm in diameter, (C) bar (width 5 mm) with 2×5 mm screws at both ends separated by 21 mm, and (D) standard BAHA screw with a diameter of 4.5 mm. Attachments A-C are shown in Fig. 1b, and the transducer mounted on one of the adaptors can be seen in Fig. 1d. The four attachments were tested sequentially on each side of each subject from the least to the most surgically invasive, in the following chronological order: D, A, B, and C. Adaptor D was implanted 55 mm from the center of the external auditory canal in the parietal bone at the typical BAHA position. Adaptors A and B were fixed via 1.2×3 mm screws fastening a 3-armed silicon sealed metallic band in the center of a shallow recess (1–2 mm deep) in the mastoid part of the temporal bone, 25 mm from the center of the outer ear canal, as seen in Fig. 1c. A thin layer of clay material was squeezed between the adaptors A and B and the skull surface to ensure flat contact over the whole area. Adaptor C was positioned such that the securing screws were on the border of the previously drilled recess. Fig. 1a illustrates schematically the adaptors' position relative to the outer ear canal and the different regions of the skull bone. More details about the implantation and technical specifications of adaptors A-C can be found in Rigato et al. (2018), Table 2. After implantation, the stability of the adaptors was verified through impedance measurements (unpublished data).

All the adaptors provide a direct-drive stimulation to the skull bone, with the main difference that adaptor D is meant to be used for percutaneous devices, while the other three are alternatives for active transcutaneous implants. Active transcutaneous applications allow for implantation of the transducer closer to the cochlea, on the mastoid bone, whereas the percutaneous BAHA has to be implanted further away on the parietal bone to avoid contact of the external unit with the pinna. To highlight this difference in position and intended use, throughout the manuscript, A, B and C will be addressed as mastoid adaptors, and D as parietal.

3.3. Objective measurements

The vibration transmission was evaluated in terms of two objectively measured quantities: velocity at the cochlear promontory, and ear canal sound pressure (ECSP).

The ECSP level was measured in both ear canals simultaneously, providing ipsilateral and contralateral measurement data from a single stimulation. On each side, a low noise ER-10B + microphone (Etymotic Research, Inc., Elk Grove Village, IL, USA) was inserted in the ear canal via a conical eartip (ER10D-T04, Etymotic Research, Inc.), kept in place by expanding polyurethane foam Sika Boom S All Seasons (Sika Sverige AB, Spånga, Sweden). The expanding foam was applied 30 min before measurements to guarantee complete drying before usage. This method was previously tested and proven to ensure support and fixed position of the microphone-holding cone and to improve isolation of external noise leakage during measurements (Rigato et al., 2018). The set-up, pointed out by an arrow in Fig. 1c, was confirmed stable in a test-retest repeatability investigation where the probe microphone was removed and reinserted repeatedly. This is important as the vibrational measurements using the laser beam require an open ear canal for reflection at the promontory, and shift between LDV and microphone had to be done several times to test the four adaptors one by one. Both microphones were calibrated in an anechoic chamber B&K 4222 (Brüel and Kjaer, Nærum, Denmark) with the sensitivity determined with a GRAS Type 42AB sound level calibrator (G.R.A.S. Sound & Vibration, Holte, Denmark). The ECSP is presented in the figures as normalized for 1 N input stimulation (dB rel 20 uPaN^{-1}).

Velocity of the cochlear promontory was measured with a CLV-2534 (Polytech, Waldbroonn, Germany) unidirectional laser Doppler vibrometer (LDV). The laser beam was directed to the cochlear promontory through the inserted ear cone, which contributed to limiting the possible incidence angle and thus the variability between measurements. Before the cone was put in place, the tympanic membrane, the malleus and the incus were removed to open the line of sight, and a small reflector of approximately 1 mm^2 was glued on the promontory. Due to the availability of one single laser instrument, ipsilateral and contralateral measurements for the same stimulation method and position were performed on two separate occasions. The instrument sensitivity was set to 5 $mms^{-1}V^{-1}$ and results are presented as normalized to 1 N input stimulation (dB rel 1 $mms^{-1}N^{-1}$).

While the adaptors were tested sequentially (D, A, B, and C) on each side, the order of measurements with each adaptor (LDV ipsilateral, LDV contralateral, and ECSP) was randomized for every set of measurements. Noise floor was recorded at the beginning of the two measurement sessions.

3.4. Data analysis

Data were analyzed mostly in relative terms by looking at the difference in response (I) between different adaptors, and (II) between ipsilateral and contralateral measurements.

Each ipsilateral measurement was considered independent from the others, leading to a total of eight repetitions for each stimulation condition (two for each head). The results are shown and analyzed in terms of both mean and median values. The average was calculated as the arithmetic mean on the data

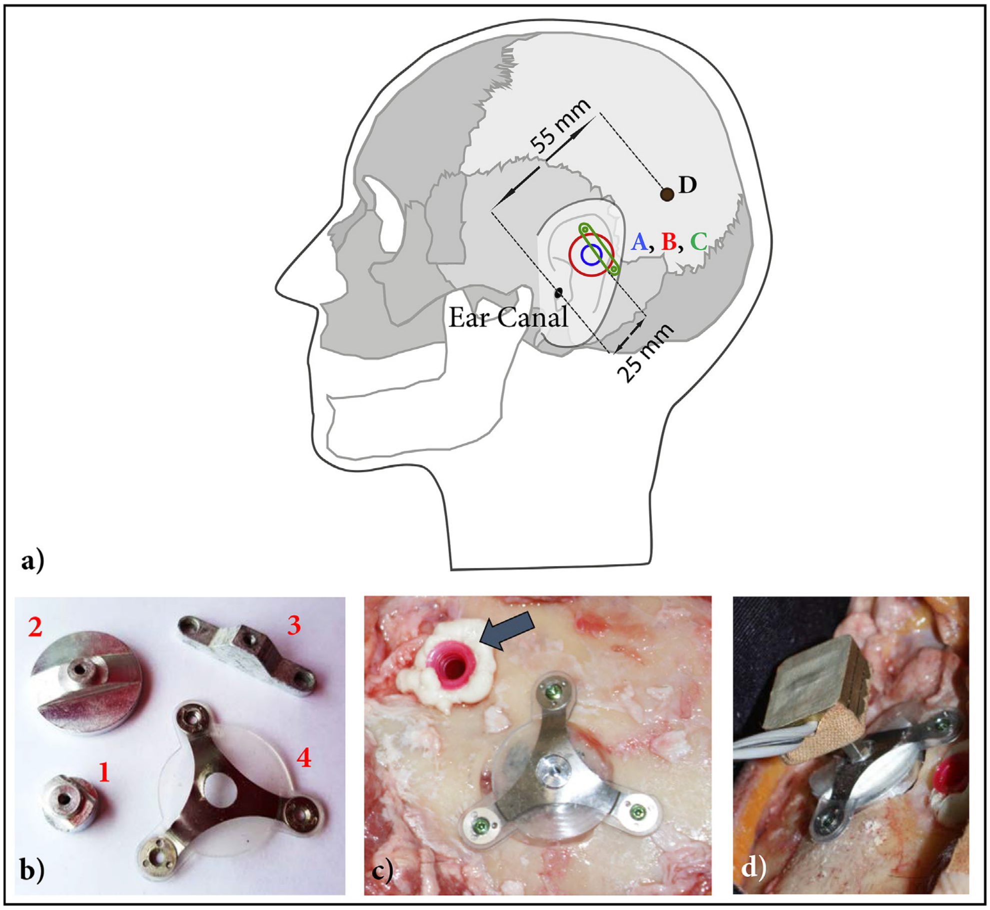

Fig. 1. a) Schematic representation of the position of the four adaptors, outlined with small blue circle (adaptor A), red circle (B), green bar (C) and brown dot (D). The distance to the external auditory canal is indicated with arrows. b) Picture of adaptors A (#1), B (#2), C (#3), and the three-armed band (#4) used to fasten adaptors A and B to the bone. c) Adaptor A in place, secured with the three-armed band. The arrow indicates the ear cone for microphone measurements, kept in place with expanding silicon foam. d) The transducer screwed on one of the adaptors. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

expressed in dB, corresponding to a geometric mean of the data in a linear scale. The 95% confidence interval around the mean value was used to evaluate the accuracy of the estimate and to determine the statistical significance of the difference between two mean values, considered statistically significant if the interval does not include zero. This analysis was performed when comparing pairwise the three mastoid adaptors, namely A-B, A-C, and B–C, for each measured frequency separately. The method is analogous to the one utilized in the previous study (Rigato et al., 2018) in order to allow for a straightforward comparison of the results.

Contralateral measurements could not be considered independent from each other on the two sides of the same subject, mainly due to anatomical reasons: while the two ipsilateral paths (from stimulation to ipsilateral cochlea) are not intersecting each other, the two contralateral paths share the region in between the left and right stimulation positions. Therefore, measurements on the same subject were pooled together to obtain the average transmission, leading to one contralateral response for each head under each stimulation condition. Due to the small sample size, contralateral data was not analyzed in terms of confidence interval.

As not all the data sets could be analyzed with parametric tests (such as the confidence interval method), the nonparametric Wilcoxon signed rank test was used as an additional tool to test the statistical significance of between-adaptors differences in three frequency ranges: 0.1–1 kHz (low-frequencies), 1–5 kHz (mid-frequencies) and 5–10 kHz (high-frequencies). Each pair of data points within the analyzed frequency bands was assumed to be conditionally independent with respect to frequency. Bonferroni correction for multiple comparisons (36 in total) was applied to the results. The test was used to detect differences greater than 2 dB in the LDV measurements and 3 dB in the microphone measurements, both ipsilaterally and contralaterally. The significance threshold values were chosen after the approximation of the test-retest coefficient of repeatability, calculated to 1.73 dB for LDV and 3.05 dB for microphone measurements. This coefficient corresponds to the smallest measurable variation that is likely to be due to an actual difference in the tested conditions rather than due to the test-retest variability.

TA was calculated as the difference between ipsilateral and contralateral response given the same stimulation level at the same site. By this definition, a positive TA corresponds to a stronger response on the ipsilateral side when compared to the contralateral one. Being the TA dependent on both ipsilateral and contralateral measurements, only four independent measurement sets were collected (one for each head). As previously stated, this sample size was not considered large enough to justify the application of statistical methods when testing the difference between the adaptors' responses. Visual inspection was used also in this case as the main analysis tool.

Test-retest variability for both ECSP and velocity measurement were thoroughly investigated in the previous study. Repeated measurements were performed in this study as well, and the results confirmed the low variability found previously, with an even improved stability in the LDV measurements. No further analysis of the test-retest variability was deemed necessary.

Data handling and statistical analysis were performed with MATLAB R2018b (MathWorks Inc, Massachusetts, USA).

4. Results

4.1. Mastoid adaptors: A, B, C

The noise floor was recorded in the beginning of each measurement session. All the LDV measurements resulted in a positive signal-to-noise ratio (SNR) except for one data point from adaptor C at 8.3 kHz and five data points from adaptor D corresponding to isolated negative peaks between 7 and 9 kHz. Furthermore, up to approximately 5 kHz, the great majority of the data had a SNR greater than 20 dB.

ECSP measurement showed a poor SNR at frequencies below 200 Hz, and therefore the frequency range for the analysis of these measurements was restricted between 0.2 and 10 kHz, where the SNR was positive. For the selected frequency range, the great majority of data points had a SNR greater than 10 dB, with the exception of few data points from adaptor D at the contralateral side, which was 0–10 dB between 0.2 and 0.3 kHz. As an overall trend, ipsilateral measurements showed a greater SNR thanks to the generally higher signal level compared to contralateral data. All the data points in the range 0.1–10 kHz for LDV and 0.2–10 kHz for microphone measurements were included in the statistical analysis.

In line with previous measurements, ECSP and cochlear promontory velocity showed a high inter-subject variability. As an example, Fig. 2 shows a dot plot of the collected data in terms of ECSP at the ipsilateral and contralateral side at selected frequencies, meant to represent low-, mid-, and high-frequency samples. As seen in Fig. 2, the between-subjects variability was greater for 8 than for 0.5 and 2 kHz. This trend was seen in LDV measurements as well, although with smaller absolute values. The mean (median) between-subjects difference for ECSP measurements was calculated to 22.9 (21.2) dB ipsilaterally and 19.8 (18.7) dB contralaterally, and for LDV measurements 9.2 (8.1) dB ipsilaterally and 9.7 (7.9) dB contralaterally.

Partly due to the high inter-subject variability, the data analysis is carried out in relative terms, thus not showing absolute magnitude values but rather differences between (I) response elicited by two different adaptors, and (II) response at ipsilateral and contralateral side elicited by the same adaptor, illustrated in Figs. 3 and 4, respectively.

Fig. 3 shows a pairwise comparison of adaptors A, B, and C for ipsilateral measurements. Mean and median values are indicated with blue thick solid and dashed lines, respectively, and represent the difference between the response from the two adaptors being compared: a positive value indicates higher response from the first adaptor and vice versa for negative values. The mean and its 95% confidence interval are calculated on eight data points for each frequency (one for each subject side), and frequency bands where the difference was found statistically significant are highlighted with a green color. Despite the high variability of measurements causing the confidence intervals to be fairly wide, trends can be identified from the plots in both LDV and microphones measurements, with good agreement between the two measurement methods. Some discrepancies are found in the lower frequency range, and possible reasons are addressed in the discussion section. For low and mid frequencies, up to approximately 5 kHz, adaptors A and B seem to give comparable transmission efficiency, with C somewhat lower. For higher frequencies, on the other hand, adaptor C appears more effective than both A and B, seen in the negative values the central and rightmost plots of Fig. 3, especially around 6 kHz. For the same frequency range, adaptor A leads to higher transmission when compared to adaptor B.

The 95% confidence interval analysis was not carried out on contralateral measurements due to the insufficient number of data points (four for each frequency, one per subject). The data was in this case analyzed with Wilcoxon signed rank test over three broader frequency bands, and the results are presented in Table 1. Analogous pairwise comparisons as in Fig. 3 are investigated, for both ipsi and contralateral measurements, and the differences were tested for being greater than 2 and 3 dB for LDV and microphone measurements, respectively. The results summarized in the table confirm that the main differences are found at high frequencies, as was pointed out in Fig. 3.

4.2. Mastoid adaptors: transcranial attenuation comparison

Transcranial attenuation (TA) was estimated as the difference between signal level measured at the ipsilateral side compared to the contralateral side with the stimulus from the same position and adaptor. Fig. 4 shows average TAs obtained with adaptors A, B, and C, and the pairwise difference between them based on data obtained with the LDV. Microphone measurements led to analogous results and are therefore omitted. In the figure, a positive TA indicates that the level at the ipsilateral side is higher than the contralateral one, in other words it shows that there was an attenuation of the signal during its transfer to the opposite side. From the top plot, it can be seen that TA is minimal for low frequencies, negative at 300–500 Hz (most likely due to the antiresonance of the skull in that frequency region), and starts to increase from 600 Hz, with steeper rise above 2 kHz approximately. The results from the three adaptors show similar behavior, with peaks of approximately 20 dB between 6 and 8 kHz.

The three lower panels of Fig. 4(b, c, d) show a more detailed pairwise comparison, where the mean and the median differences are plotted together with the single values at selected audiometric frequencies. The transmission is fairly similar in low and mid frequencies, while above 6 kHz adaptor C shows 5–10 dB lower attenuation compared to A and B. The data from individual specimens, plotted with blue circles, indicate a low inter-subject variability, meaning that despite great variations in the absolute measured values, the difference between ipsi and contralateral side measurements is consistent among the four subjects. This tends to increase at higher frequencies, where differences of more than 10 dB can be observed between subjects.

4.3. Mastoid vs parietal attachments: A, B, C vs D

Fig. 5 shows a comparison between the three mastoid adaptors (A, B, and C) and the parietal one (D). The average TA obtained from microphone measurements is plotted in the panel a, where a difference can be noticed. Except for frequencies below 400 Hz, the TA for adaptor D is close to zero throughout the whole frequency range, while the other adaptors show a positive TA from approximately 1 kHz and upwards, as already pointed out in Fig. 4. Fig. 5b shows the TA of adaptors A, B, and C normalized to adaptor D, to highlight the difference in TA between mastoid and parietal adaptors. When looking at the measurements obtained ipsilaterally and contralaterally separately (Fig. 5c and d), it can be noticed that the difference in TA is mainly due to the difference in ipsilateral transmission, where adaptor D results in a consistently lower (10–20 dB) response compared to the mastoid adaptors.

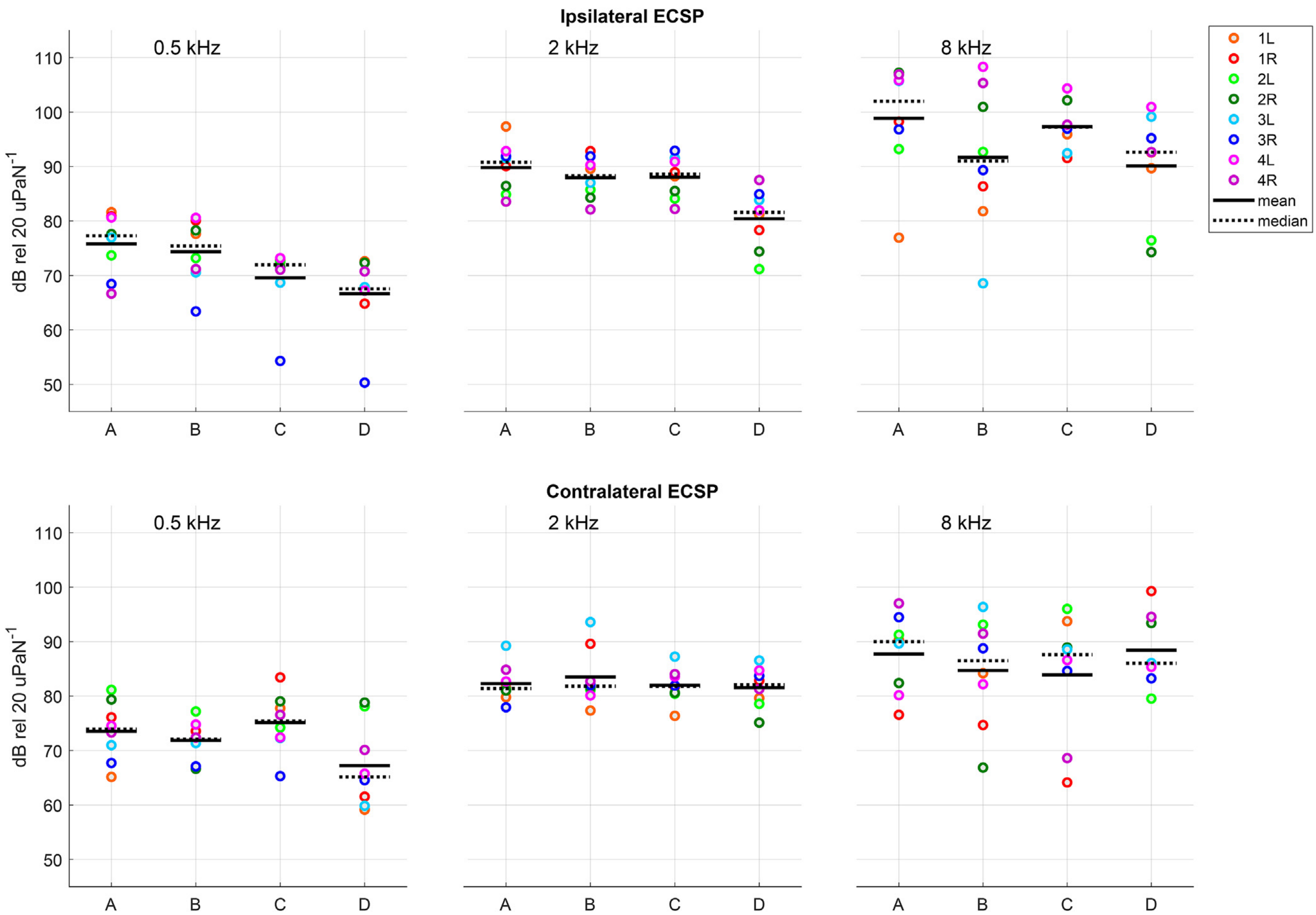

Fig. 2. Plot of the data obtained from the ECSP (ear canal sound pressure) measurement at three sample frequencies: 0.5, 2 and 8 kHz. The top row shows data measured on the same side as the stimulation (ipsilateral), the bottom row shows contralateral measurements. Data points for single stimulations (1L = subject 1, stimulation on left side, 1 R = subject 1, stimulation on right side, and so on) are plotted for each adaptor, A to D. Mean and median values are included as solid and dashed lines, respectively. The values are normalized for 1N input stimulation.

5. Discussion

5.1. Measurement methods

Vibration transmission by direct-drive BC stimulation was investigated in this study, where the measured outcomes were ECSP and velocity at the cochlear promontory. In a clinical perspective, the effect under investigation is relevant if it influences the rehabilitation quality provided by the device when fitted in a patient. Objective measurements can be used as indirect estimate of relative hearing rehabilitation effect with the underlying assumption that they are strictly correlated to hearing ability. Indeed, previous studies have demonstrated that shifts in vibrational level at the cochlea and in the ear canal correspond to shifts in hearing perception (Eeg-Olofsson et al., 2013; Reinfeldt et al., 2013, 2014), with increased vibrational level corresponding to increased hearing sensation. However, this relation has not been quantified yet, so the clinical significance is still uncertain. Also, it should be emphasized for the following discussion that, from a hearing perspective, the degree of stimulation of the basilar membrane for different vibrating directions is unknown.

For an indirect estimate of the hearing rehabilitation effect, both LDV and microphone measurements are expected to be in agreement with each other. As seen in Fig. 3, results are consistent in most frequency ranges for all pairwise comparisons. This is seen if looking at the significance bands (highlighted with green color) and also more generally from the increase/decrease pattern. The main differences between velocity and sound pressure measurements are found at low frequencies, where the microphone seems to be able to detect variations which are missed by the LDV. This discrepancy was already observed in previous studies (Reinfeldt et al., 2014; Rigato et al., 2018) and was hypothesized to depend upon the three-dimensional sensitivity of ECSP measurements compared to the uni-dimensional one of the LDV. However, the direction of measurement used in this study, i.e. approximately perpendicular to the skull, was shown to be the highest component in the total 3D acceleration level recorded at the cochlear promontory for low frequencies before the first antiresonance (400–500 Hz), and even at higher frequencies if the stimulation position was close to the cochlea (Stenfelt and Goode, 2005). Also Dobrev et al. (2018) described the perpendicular direction under BC stimulation at the mastoid position as slightly superior to the other ones. The unidimensional LDV measurements are therefore considered well representative of the cochlear vibratory pattern when comparing adaptors A, B, and C. When the stimulation is at the parietal bone (adaptor D), however, the unidirectional LDV data might not be as representative of the cochlear vibratory pattern as the microphone. As shown in Dobrev et al. (2018), when the stimulation is at the BAHA position, the perpendicular direction is bigger only up to 500 Hz, and the tangent directions become more influential at mid and high frequencies, as seen also in Stenfelt and Goode (2005). This highlights a change in the relative importance

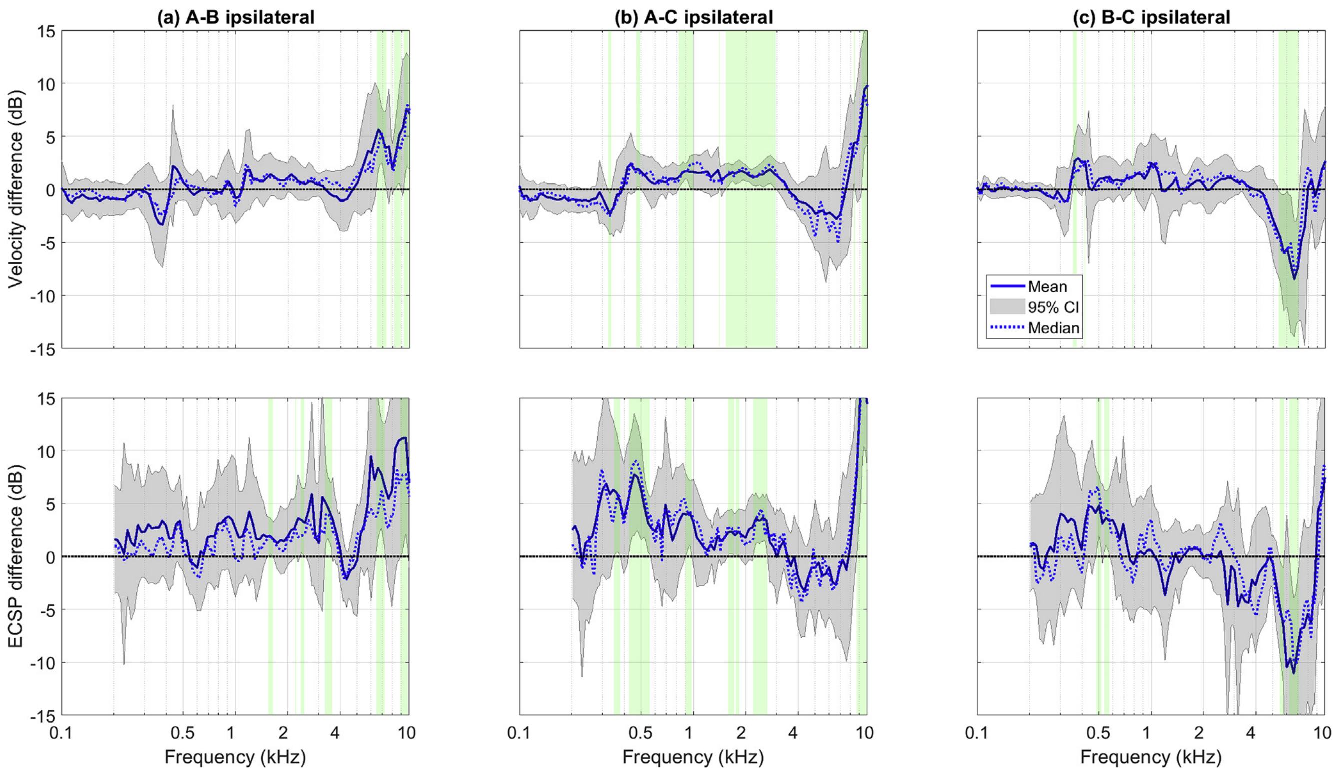

Fig. 3. Average difference in cochlear promontory velocity (top row) and ear canal sound pressure (ECSP, bottom row) for (a) adaptor A minus B, (b) A minus C and (c) B minus C at the ipsilateral side. The shaded grey areas show the 95% confidence interval (CI), and significant differences are highlighted with green color. Mean and median are shown as thick solid line and dashed line, respectively. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

of the components in the three-dimensional space when the stimulation is moved from the mastoid to the parietal position, which may imply that potentially misleading conclusions may be drawn by looking only at one component. Therefore, in this study, despite the lacking knowledge of the discrepancy between LDV and ECSP results, the data obtained with the microphones is preferred when comparing results from adaptors A, B, and C with adaptor D (Fig. 5). To a certain extent, this choice is supported by the study by Reinfeldt et al. (2014), where ECSP shift was found to reflect the hearing threshold shift below 500 Hz when comparing BAHA vs mastoid position, whereas LDV measurements did not.

During ECSP measurements, the ear canals were occluded by the microphones, as opposed to the open condition during LDV measurements. Blocking of the ears may cause occlusion effect, i.e. an increased pressure in the ear canals in frequencies below 500–2000 Hz, less prominent if the occlusion depth is increased (Stenfelt and Reinfeldt, 2007). This effect has been found to be higher at the contralateral side (Reinfeldt et al., 2013), which may potentially cause an underestimation of the TA in certain measurement conditions. On the other hand, it has also been shown that removal of middle ear tissues and tympanic membrane reduces the occlusion effect (Stenfelt et al., 2003). The absence of the tympanic membrane and parts of the middle ear structures in the utilized specimens, combined with the deep insertion of the microphone in the ear canal opening during measurements, minimize the risk of occlusion effect, which is therefore excluded as a potential difference between LDV and ECSP measurements. Additional factors causing discrepancies between the two measurement methods may be e.g. the susceptibility to external noise (in forms of vibrations or acoustic noise), or the presence of standing waves in the ear canal, as suggested by Ravicz et al. (2014). However, such factors were not investigated in this study and are therefore not discussed further.

As mentioned above, all the measurements were performed after removing parts of the middle ear, including the tympanic membrane, the malleus and the incus. The absence of the middle ear ossicles may affect BC sound transmission in the frequency range between 1.5 and 3.1 kHz (Stenfelt, 2006), where the oval window seems to be one of the key pathways for BC sound transmission. However, the influence of the alteration of the middle ear structures is believed to have an effect only on the measured absolute values, and not on the relative increase/decrease of sound pressure and cochlear promontory motion.

5.2. Mastoid adaptors

The results shown in Fig. 3 confirm the previous findings from Rigato et al. (2018) on the ipsilateral transmission of vibrations. Despite the high inter-subject variability, the group results resemble the previous ones, strengthening the study conclusions. The effect of transducer attachment is seen mainly at high frequencies, both ipsilaterally and contralaterally. More power output in high frequencies can significantly improve speech understanding, and it is therefore an advantage to have an efficient transmission in this range. The better performance at high frequencies (5–8 kHz) of the double screw attachment (adaptor C) compared to the flat ones (A and B) was hypothesized to be caused by a stiffer attachment to the bone provided by the larger screws. In a clinical application, while screws might give a benefit in transmission, they will most likely be osseointegrated, and might constitute a drawback in a potential need to explant the device. For example, if a MRI investigation would be needed, the implanted unit might have to be removed to avoid large distortions in the diagnostic image and potential hazard to patients in the strong magnetic field generated

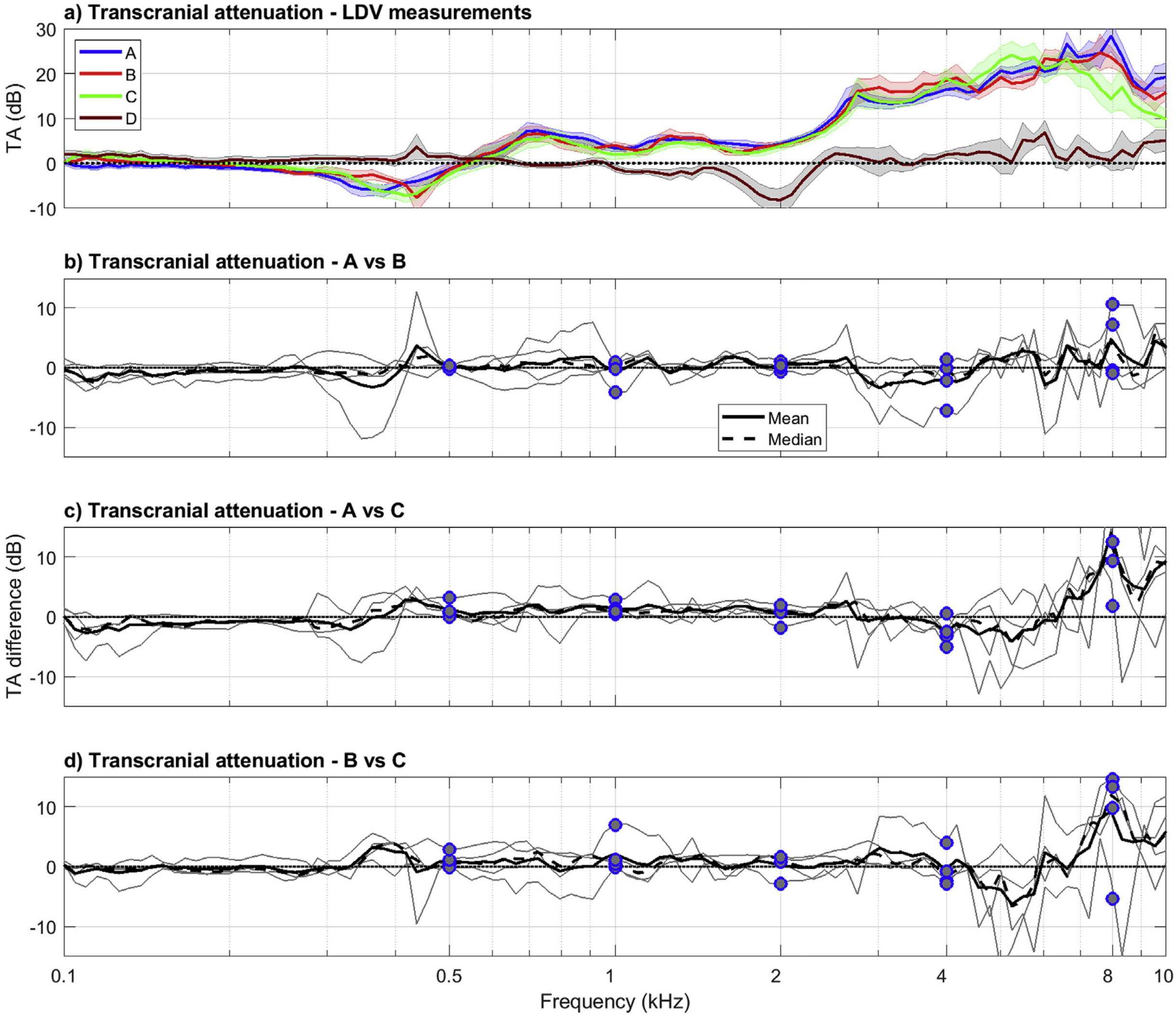

Fig. 4. a) mean transcranial attenuation (TA) for adaptors A- D obtained from laser measurements. The shaded area indicates ± one standard deviation interval. b) difference in TA for adaptors A minus B, c) A minus C, and d) B minus C. Mean and median values are plotted as solid and dashed line, respectively. Values for single heads are plotted as thin grey lines, and as circles for selected audiometric frequencies: 0.5, 1, 2, 4, and 8 kHz.

Table 1
Results for Wilcoxon signed rank test with Bonferroni correction for multiple comparisons (N = 36) on ipsilateral (ipsi) and contralateral (contra) data in three frequency regions: LF = low frequencies (0.1–1 kHz for LDV measurements, 0.2–1 kHz for microphone measurements), MF = mid frequencies (1–5 kHz), and HF = high frequencies (5–10 kHz). Differences of more than 2 dB were looked for in laser Doppler vibrometer (LDV) measurements, 3 dB for microphone measurements. Statistically significant results (after the Bonferroni correction) are indicated in bold font, NS = not statistically significant. Test statistics and p-value are indicated in brackets.

		A vs B	A vs C	B vs C
LDV ipsi	LF	NS (76533, p = 1)	NS (81741, p = 1)	NS (65002, p = 1)
	MF	NS (32806, p = 1)	NS (30867, p = 1)	NS (42491, p = 1)
	HF	**significant (24041, p = 8.5e-17)**	**significant (26570, p = 3.05e-26)**	**significant (28153, p = 2.6e-33)**
LDV contra	LF	NS (64674, p = 1)	NS (48669, p = 1)	NS (42553, p = 1)
	MF	NS (59397, p = 1)	NS (28589, p = 1)	NS (48753, p = 1)
	HF	**significant (25994, p = 6.8e-24)**	**significant (29064, p = 9.0e-38)**	**significant (28608, p = 1.7e-35)**
mic ipsi	LF	NS (65825, p = 0.9995)	**significant (98733, p = 6.8e-08)**	**significant (93446, p = 5.0e-05)**
	MF	NS (72579, p = 0.8994)	NS (60054, p = 1)	NS (73968, p = 0.8191)
	HF	**significant (23898, p = 2.5e-16)**	**significant (26118, 2.2 e-24)**	**significant (27958, p = 2.2e-32)**
mic contra	LF	NS (86745, p = 0.0167)	NS (87373, p = 0.0106)	**significant (108394, p = 3.3e-15)**
	MF	NS (79361, p = 0.3046)	NS (83226, p = 0629)	NS (59191, p = 1)
	HF	**significant (19184, p = 6.1e-5)**	**significant (24701, p = 4.8e-19)**	**significant (23793, p = 5.4e-16)**

by MRI scanners (Fredén-Jansson et al., 2015). It is therefore important to bear in mind that several factors should be taken into account when evaluating a design for active transcutaneous BCDs.

When looking at the flat contact area, a smaller one seems to give better transmission (Fig. 3a), although the effect is not very clear for low and mid frequencies. The reason for the loss of transmission with increased contact area might be that it is more difficult for the transducer to flex a wider surface, especially at

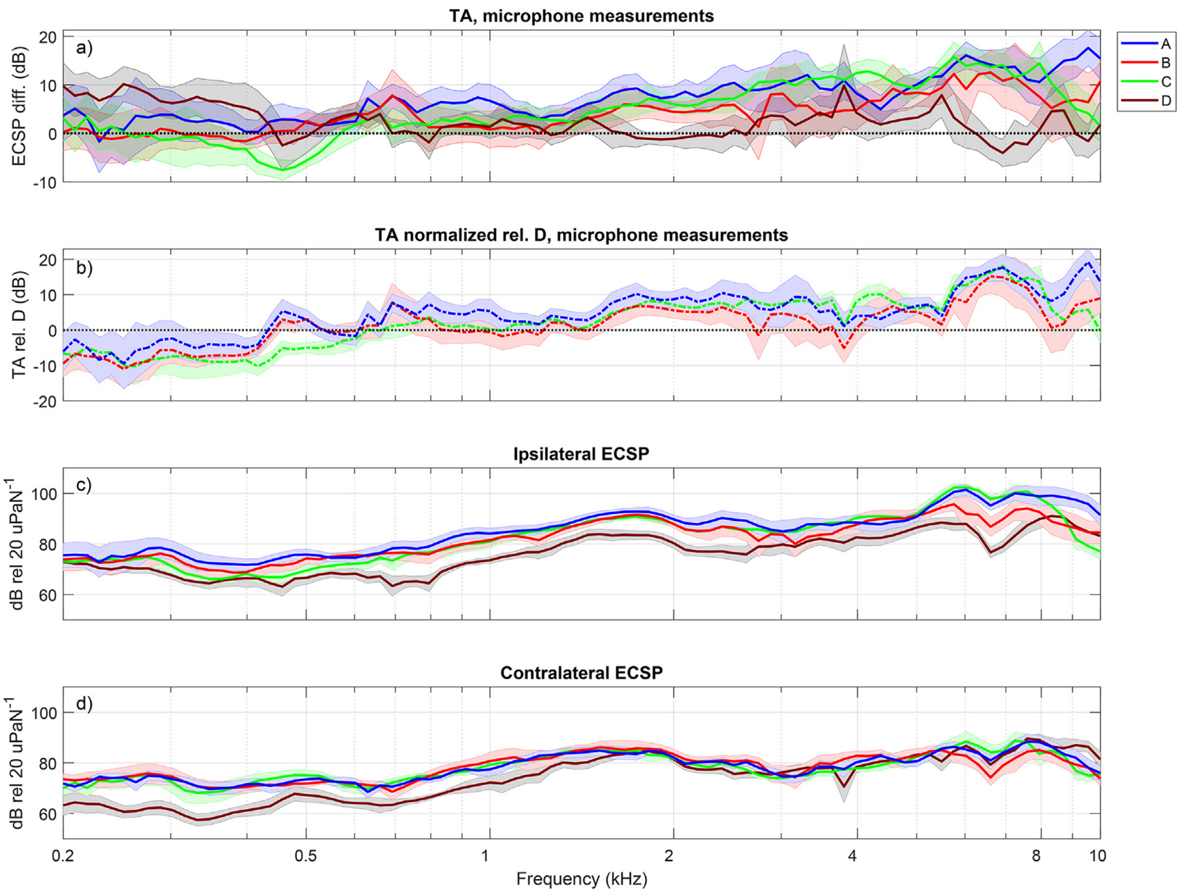

Fig. 5. a) transcranial attenuation (TA) obtained with adaptors A-D from measurements with the inserted microphones. b) TA of adaptors A, B, and C normalized to adaptor D. Ipsilateral and contralateral mean transmission are shown separately in the c) and d) panels, respectively. The shaded areas around the mean curves indicate ± one standard deviation. ECSP (ear canal sound pressure) values are normalized to 1 N input stimulus. Frequency is restricted between 0.2 and 10 kHz to show only data points that were recorded above the noise floor.

higher frequencies. Another factor could be that the wide contact to the bone is difficult to maintain when stimulating at high frequency. Partial loss of contact between the flat surface of the transducer and the bone may occur during vibration. In a live human situation one can only speculate but a possible bone adaptation to the flat surface with a thin layer of fluid in between may imply more effective transmission than is possible to simulate in this study. For the double screw attachment a similar adaptation seems unlikely due to the firm arrangement at implantation. On the other hand, a wider but flatter implant may have the advantage of requiring less implantation depth, thus making the surgery procedure simpler and faster, provided that the curvature of the skull allows for a maximum contact area without the need of excessive drilling to even out the surface.

5.3. Contralateral transmission and transcranial attenuation

The transmission of the signal to the contralateral ear can be studied in absolute terms (i.e. looking only at the contralateral signal level, regardless of the ipsilateral response), or in relative terms (TA, where ipsilateral and contralateral responses are compared to each other). The contralateral response in absolute terms is of interest e.g. if the BCD is used for rehabilitation of SSD patients, when the device is positioned on the deaf side to pick up the sounds and transmit the signal over to the contralateral side to utilize the healthy cochlea. In this application, a strong contralateral response is desirable. In Fig. 5d, the contralateral response of the mastoid adaptors (A-C) is seen to be comparable to the one given by the parietal adaptor (D), and even higher at frequencies below 1 kHz, suggesting that they would likely yield a similar rehabilitation effect in SSD patients. However, in a complete active transcutaneous BCD, the signal would have to be transmitted over the skin via an inductive link, and its potential loss of power should also be taken into account if the full BCD systems were to be compared. On the other hand, when considering the use of BCDs for unilateral or bilateral implantation in patients with conductive or mixed hearing loss at the implanted side, the goal should be to minimize the transmission of the signal to the contralateral side as compared to the ipsilateral, and a high TA would therefore be desirable. Crossover during BC stimulation limits the sound separation in terms of time and level difference at the cochleae, leading to a decreased ability in tasks requring binaural hearing (Stenfelt and Zeitooni, 2013; Zeitooni et al., 2016).

Fig. 4a shows that the TA estimated from LDV measurements for the three mastoid adaptors is on average around 5 dB between 0.6 and 2 kHz, and up to 10–20 dB for higher frequencies. When the microphone measurements are used to estimate the TA (Fig. 5), the resulting values are approximately 5 dB higher than the LDV ones at low and mid frequencies, and 5–10 dB lower in the high frequency region. Furthermore, in microphone measurements a more noticeable difference is seen between the three mastoid adaptors, with adaptor B showing 2–3 dB lower TA compared to adaptors A and C. The difference in the values obtained with LDV and microphone measurements suggest that orthogonal components, which are not captured by the LDV, are present in different extent at the ipsilateral and contralateral cochleae.

When looking at the TA estimated with stimulation at the parietal position, the results are mostly in line with previous findings from LDV measurements. A negative TA between 0.5 and 1 kHz has been observed e.g. in Stenfelt et al. (2000), where it was attributed to the effect of an anti-resonance in the ipsilateral transmission path. Lower vibration levels were detected at the ipsilateral side as compared to the contralateral one also for frequencies bellow 500 Hz in Stenfelt and Goode (2005) and more recently in Dobrev et al. (2018), who show a TA of −6 to −2 dB in the frequency range 250–500 Hz with stimulation at the BAHA position. In Eeg-Olofsson et al. (2011), on the other hand, the estimated TA was approximately zero in most of the frequencies between 0.1 and 10 kHz, with slightly negative TA even for frequencies in the upper range.

In Fig. 5b, the stimulation at the parietal bone via adaptor D is shown to give a 5–10 dB lower TA for frequencies above approximately 500 Hz when compared to adaptors A, B, and C. The difference in TA is thought to be mainly due to the stimulation location rather than to the attachment type. This assumption is based on previous studies on the dependency of TA on stimulation location, which have shown lower TA at the BAHA location compared to the mastoid one (Dobrev et al., 2018; Eeg-Olofsson et al., 2011; Reinfeldt et al., 2014; Stenfelt, 2012). Fig. 5 also confirms previous findings showing that the mastoid position gives higher vibrational level at the ipsilateral cochlea compared to the parietal position (Eeg-Olofsson et al., 2008; Stenfelt and Goode, 2005), and that the difference in TA is mainly due to this difference in ipsilateral signal level. To achieve a higher signal separation between the two cohleae, the stimulation at the mastoid position appears therefore superior to the parietal bone position. However, given that the TA seems to be mainly dependent on the implant location, it is important to consider where the different adaptors would be implanted in the clinical application. The final position of the implant may change from device to device and also between individuals, due to the anatomical characteristics of the skull bone combined with the design characteristics of the implantable unit.

6. Conclusions

The vibration response under direct-drive BC stimulation was measured ipsilaterally and contralaterally for four different transducer attachments. Measurements were taken with LDV and probe microphone, and a general agreement between the two methods was found. Three of the tested adaptors, named A, B, and C, were meant for transcutaneous stimulation and were positioned at the mastoid part of the temporal bone, while D was the classic BAHA screw attachment, positioned in the parietal bone.

The comparison between the mastoid adaptors A, B, and C agreed with previous findings, confirming that: (1) A twin-screw attachment seems to give the most effective transmission for frequencies around 6 kHz, but somewhat lower in the mid frequency range, and (2) keeping a smaller contact area shows advantages compared to a more extended one, in both mid and high frequencies. The same trends were seen ipsilaterally and contralaterally, although the ipsilateral effect is more distinct.

The TA, estimated as level of ipsilateral minus contralateral signal given the same stimulation position and intensity, was found to be similar for adaptors A, B, and C, with values up to 20 dB at high frequencies. A lower TA was seen when adaptor D was used, mainly due to a lower ipsilateral response. Based on the measured TA and absolute contralateral response values, the position and attachment procedure of adaptors A-C seem to be equally suitable for SSD patients rehabilitation as the D solution, while also providing a more side-specific stimulus, i.e. likely facilitating interaural separation.

Funding

This study was mainly supported by The Swedish Research Council.

Disclosure

The co-authors Sabine Reinfeldt, Bo Håkansson, and Måns Eeg-Olofsson act as consultants for Oticon Medical. The remaining authors report no conflicts of interest.

Contribution from each author

Rigato, Cristina: contributed to the design of the study, performed measurements, data analysis and visualization, and wrote most of the manuscript.

Reinfeldt, Sabine: contributed to the design of the study, performed measurements, and provided support in the interpretation of the results and in the writing process.

Håkansson, Bo: contributed to the design of the study, performed measurements, and provided support in the interpretation of the results and in the writing process.

Fredén Jansson, Karl-Johan: performed measurements, and provided support in the writing process.

Renvall, Erik: participated to the preparation of the study, performed surgeries, and provided peer-support in the writing process.

Eeg-Olofsson, Måns: contributed to the design of the study, performed surgeries, and provided support in the discussion of the results and in the writing process.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heares.2019.06.006.

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